

What is claimed is:

1. A syringe assembly comprising:
  - a syringe barrel having an inside surface defining a chamber, an open end, and a distal end;
  - 5 a plunger rod extending within said syringe barrel, said plunger rod including an elongate body portion defining a longitudinal axis, a stopper at a distal end of said elongate body portion, a disc, and at least one axially extending recess formed by a pair of surfaces radially displaced from the longitudinal axis of said elongate body portion, each of said surfaces defining at least one proximal tooth and at least one distal tooth, said plunger rod  
10 being substantially immovable after performing a first retraction stroke in the direction of said open end, a first injection stroke in the direction of said distal end, a second retraction stroke in the direction of said open end and a second injection stroke in the direction of said distal end; and
  - a locking element slidably positioned within said recess, said locking element  
15 engaging said inside surface of said syringe barrel such that said locking element is substantially immovable in the direction of the open end of said syringe barrel, said locking element further being engageable with said at least one proximal tooth during said first injection stroke of said plunger rod and said locking element being engageable with said at least one distal tooth during said second injection stroke of said plunger rod .
- 20 2. The syringe assembly of claim 1, wherein said barrel further defines an annular ring for limiting movement of said plunger rod in the direction of said open end.
3. The syringe assembly of claim 2, wherein said plunger rod movement is limited in the direction of the open end during said first retraction stroke when said stopper abuts a said annular ring.

4. The syringe assembly of claim 2, wherein said plunger rod movement is limited in the direction of the open end during said second retraction stroke when said stopper abuts a said annular ring.

5. The syringe assembly of claim 1, wherein said at least one proximal tooth comprises a plurality of proximal teeth and said at least one distal tooth comprises a plurality of distal teeth.

6. The syringe assembly of claim 1, wherein said at least one proximal tooth comprises three teeth.

7. The syringe assembly of claim 1, wherein said at least one distal tooth comprises three teeth.

8. The syringe assembly of claim 1 wherein said locking element is comprised of an integral, resilient metal structure, said locking element being positioned such that said plunger rod can be moved proximally with respect to said locking element.

9. The syringe assembly of claim 1 wherein said locking element includes one or more proximally extending barbs engaging said inside surface of said syringe barrel, and said locking element and stopper are positioned such that said plunger rod can be moved proximally with respect to said locking element.

10. The syringe assembly of claim 9 wherein said locking element includes a body portion having a distal end and proximal end, said body portion of said locking element being generally V-shaped and engageable with each of said pair of surfaces.

11. The syringe assembly of claim 10 including a first pair of legs extending from and deflectable with respect to said proximal end of said body portion, said legs engaging said plunger rod.

12. The syringe assembly of claim 11 including a first proximally extending barb adjacent said distal end of said body portion and a second proximally extending barb

extending from at least one of said legs, said first and second barbs engaging said inside surface of said syringe barrel.

13. The syringe assembly of claim 1 wherein said elongate body portion of said plunger rod includes a plurality of radially extending walls that converge near said  
5 longitudinal axis and a first additional wall extending from one of said radially extending walls in a non-radial direction, said first additional wall defining one of said surfaces forming said recess.

14. The syringe assembly of claim 13 including a second additional wall extending from one of said radially extending walls, said second additional wall defining one of said  
10 surfaces forming said recess.

15. The syringe assembly of claim 14 wherein said second additional wall is substantially parallel to said first additional wall.

16. The syringe assembly of claim 1 wherein said elongate body portion of said plunger rod includes a first wall proximal to said stopper and a plurality of second walls  
15 projecting from a first side of first wall, two of said second walls defining said surfaces forming said recess.

17. The syringe assembly of claim 1 wherein said annular ring is spaced a distance from said distal end such that said distance defines a volume of said chamber to be substantially equal to a desired reconstitution dose.

20 18. The syringe assembly of claim 17 wherein said locking element has a longitudinal length substantially equal to said distance.

19. The syringe assembly of claim 1 further comprising a needle cannula attached to said distal end of said barrel and in fluid communication with said barrel.

20. The syringe assembly of claim 19, wherein said needle cannula further includes a  
25 hub for removably attaching said needle cannula to said barrel.

21. The syringe assembly of claim 19, wherein said needle cannula defines a sharpened distal tip.

22. The syringe assembly of claim 19, wherein said needle cannula is permanently attached to said barrel.

5 23. The syringe assembly of claim 19, wherein said needle cannula defines a blunt distal tip.

24. A syringe assembly comprising:

a syringe barrel having an inside surface defining a chamber, an open end, a distal end and an annular ring;

10 a plunger rod extending within said syringe barrel, said plunger rod including an elongate body portion defining a longitudinal axis, a stopper at a distal end of said elongate body portion, a disc, a first axially extending recess formed by a pair of first surfaces radially displaced from the longitudinal axis of said elongate body portion, each of said first surfaces defining a plurality of teeth, and a second axially extending recess formed by  
15 a pair of second surfaces radially displaced from the longitudinal axis of said elongate body portion, each of said second surfaces defining at least one proximal tooth and at least one distal tooth; and

a locking element slidably positioned within one of said first or second recesses, said locking element engaging said inside surface of said syringe barrel such that said  
20 locking element is substantially immovable in the direction of the open end of said syringe barrel, said locking element further being engageable with said teeth.

25 25. A syringe assembly of claim 24, wherein said locking element is slidably positioned within said first recess, said locking element engaging said inside surface of said syringe barrel such that said locking element is substantially immovable in the direction of the open end of said syringe barrel, said locking element further being

engageable with said plurality of teeth such that said plunger rod and locking element can be moved distally together toward said distal end of said syringe barrel with said locking element being maintained in said recess and substantially displaced from the longitudinal axis of said plunger rod

5 26. A syringe assembly according to claim 24, wherein said locking element is slidably positioned within said second recess so that said plunger rod is substantially immovable after performing a first retraction stroke in the direction of said open end, a first injection stroke in the direction of said distal end, a second retraction stroke in the direction of said open end and a second injection stroke in the direction of said distal end.

10 27. The syringe assembly of claim 24 wherein said locking element includes one or more proximally extending barbs engaging said inside surface of said syringe barrel, and said locking element and stopper are positioned such that said plunger rod can be moved proximally with respect to said locking element.

28. A method for performing a two stroke injection procedure, comprising:

15 providing a syringe comprising a syringe barrel having an inside surface defining a chamber, an open end, a distal end and an annular ring; a plunger rod extending within the syringe barrel, the plunger rod including an elongate body portion defining a longitudinal axis, a stopper at a distal end of the elongate body portion, a disc, and an axially extending recess formed by a pair of surfaces radially displaced from the longitudinal axis of the  
20 elongate body portion, the surfaces defining at least one proximal tooth and at least one distal tooth; and a locking element slidably positioned within the recess and abutting the disc;

performing a first retraction stroke by proximally withdrawing the plunger rod so that the stopper abuts the annular ring, wherein the locking element remains substantially  
25 motionless allowing the proximal tooth to pass under the locking element;

performing a first injection stroke by distally moving the plunger rod so that the stopper abuts the distal end of the barrel and the proximal tooth abuts the locking element, wherein the locking element remains substantially motionless during the first injection stroke;

- 5 performing a second retraction stroke by proximally withdrawing the plunger rod so that the stopper abuts the annular ring, wherein the locking element remains substantially motionless allowing the distal tooth to pass under the locking element so that the locking element abuts the distal tooth;

- 10 performing a second injection stroke by distally moving the plunger rod so that the stopper abuts the distal end of the barrel, wherein the locking element moves distally with the plunger rod; and

locking the plunger rod via engagement of the locking element with the barrel and stopper rendering the syringe assembly permanently disabled.

15 #66738